



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/881,181	06/14/2001	Walter Wallach	13463-701.201	6808

21971 7590 01/18/2006

WILSON SONSINI GOODRICH & ROSATI
650 PAGE MILL ROAD
PALO ALTO, CA 94304-1050

EXAMINER

COBANOGU, DILEK B

ART UNIT

PAPER NUMBER

3626

DATE MAILED: 01/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/881,181

Applicant(s)

WALLACH ET AL.

Examiner

Dilek B. Cobanoglu

Art Unit

3626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 June 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-57 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-57 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 June 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 12/18/2001.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. Claims 1-57 have been examined.

Specification

2. Applicant is reminded of the proper language and format for an abstract of the disclosure.
3. The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.
4. The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is disclosing a method for securely collecting information from a user; but the steps of claim 1 does not provide the information about how the collection is being done.

7. Claims 2 to 19 are also rejected under 35 U.S.C. 112, second paragraph according to the dependency to the claim 1.

Claim Rejections - 35 USC § 102

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 20, 21, 22, 26, 27, 28, 29, 30, 31, 32, 33, 34, 35, 37, 38, 39, 40, 42 to 48, 49, 50, 52, 53, 54, 55, 56, and 57 are rejected under 35 U.S.C. 102(e) as being unpatentable by Sparks (U.S. Patent Publication No. 2001/0037215).

A. As per claim 20, Sparks discloses a method for collecting data (Sparks; paragraph 3), comprising:

(a) providing a medical test to a patient (Sparks; paragraph 33);

(b) collecting the testing apparatus from the user once the user completes testing (Sparks; paragraph 37); and

(c) distributing test information from the apparatus to authorized recipients (Sparks; paragraph 38).

B. As per claim 21, Sparks discloses the method of claim 20 wherein said step (a) comprises:

(a1) accepting a request to ship a test device from a requestor (Sparks; paragraph 17); and

(a2) communicating with a logistics system directing shipment of the device to the patient (Sparks; paragraph 76).

C. As per claim 22, Sparks discloses the method of claim 20 wherein said step (a1) comprises the sub-steps of: authorizing the requestor to make the request; and accepting the request (Sparks; paragraph 42).

D. As per claim 26, Sparks discloses the method of claim 20 wherein said step (a) is performed via a computer over a communications network (Sparks; paragraph 90).

E. As per claim 27, Sparks discloses the method of claim 26 wherein said communications network is a modem (Sparks; paragraph 18).

Examiner considers that since the system disclosed by Sparks includes a modem since it includes communication types such as phone, fax, and e-mail and online.

F. As per claim 28, Sparks discloses the method of claim 26 wherein said communications network is a global computer communications network. (Sparks; paragraph 39).

G. As per claim 29, Sparks discloses the method of claim 28 wherein said communications network is a wireless link (Sparks; paragraph 39).

H. As per claim 30, Sparks discloses the method of claim 20 wherein said step (c) is performed over a series of at least one private and one public network (Sparks; paragraph 39).

I. As per claim 31, Sparks discloses the method of claim 20 wherein said step (c) comprises: (c1) determining, based on input from the patient, said authorized recipient; and (c2) verifying a recipient's authorization to receive data before distributing said data (Sparks; paragraph 42).

J. As per claim 32, Sparks discloses the method of claim 20 wherein said step (c) is performed using secure communications (Sparks; paragraph 71).

K. As per claim 33, Sparks discloses the method of claim 20 wherein said step (a) is performed using secure communications (Sparks; paragraph 40).

L. As per claim 34, Sparks discloses the method of claim 20 wherein step (a) comprises the sub-steps of: (a1) receiving a request from a referring physician for a medical test, subject to verification by an authorized physician; and (a2) receiving authorization from the authorized physician (Sparks; paragraphs 16 and 77).

M. As per claim 35, Sparks discloses the method of claim 34 wherein said step (c) comprises: (c1) receiving authorization from the patient for the

referring physician to receive distributions of patient's data; and (c2) distributing the patient's data to referring physician (Sparks; paragraph 38).

N. As per claim 37, Sparks discloses the method of claim 36 wherein said steps are performed sequentially (Sparks; paragraph 87).

O. As per claim 38, Sparks discloses the method of claim 36 wherein said step (a) is performed using an information server coupled to a public network (Sparks; paragraph 39).

P. As per claim 39, Sparks discloses the method of claim 36 wherein said step (a) comprises:

(a1) accepting a request to ship a medical test device from the physician (Sparks; paragraph 17).; and

(a2) communicating with a shipper directing shipment to the patient (Sparks; paragraph 78).

Q. As per claim 40, Sparks discloses the method of claim 39 wherein said step (a1) comprises the sub-steps of: verifying the physician is authorized to make the request; and accepting the request (Sparks; paragraph 42).

R. As per claim 42, Sparks discloses the system of claim 41 wherein the interface server includes an order authorization application (Sparks; paragraph 42).

S. As per claim 43, Sparks discloses the system of claim 42 wherein the authorization application includes at least a consumer access level, a

patient access level, a member access level and a physician access level (Sparks; paragraph 41).

T. As per claim 44, Sparks discloses the system of claim 41 wherein the database server includes a data structure including a physician record data structure (Sparks; paragraph 38), a manufacturing record database (Sparks; paragraph 76), a client record database (Sparks; paragraph 75) and a device record data structure (Sparks; paragraph 76).

U. As per claim 45, Sparks discloses the system of claim 41 further including a journaling application transferring orders to the logistics system (Sparks; paragraph 76).

V. As per claim 46, Sparks discloses the system of claim 41 further including an inventory inquiry application communicating with the logistics system (Sparks; paragraph 37).

W. As per claim 47, Sparks discloses the system of claim 41 wherein the logistics system includes an interface application to a commercial shipper (Sparks; paragraph 39).

X. As per claim 48, Sparks discloses the system of claim 41 further including a device return verification application, communicating with the logistics system (Sparks; paragraph 59).

Y. As per claim 49, Sparks discloses the system of claim 41 further including a data extraction application (Sparks; abstract and paragraph 16)

Z. As per claim 50, Sparks discloses the system of claim 41 further including a data report generator (Sparks; paragraph 18).

AA. As per claim 52, Sparks discloses the method of claim 51 wherein said steps (c) and (d) are performed sequentially (Sparks; paragraph 87).

BB. As per claim 53, Sparks discloses the method of claim 51 wherein said step (d) is performed prior to said step (c) (Sparks; paragraph 87).

CC. As per claim 54, Sparks discloses the method of claim 51 wherein said step (c) is performed via said network (Sparks; paragraph 90).

DD. As per claim 55, Sparks discloses the method of claim 51 wherein said step (c) is performed via a modem.

Examiner considers that since the system disclosed by Sparks includes a modem since it includes communication types such as phone, fax, and e-mail and online.

EE. As per claim 56, Sparks discloses the method of claim 51 wherein said step (c) is performed via a wireless communications link (Sparks; paragraph 39).

FF. As per claim 57, Sparks discloses the method of claim 51 wherein said communications network is at least partially a public network (Sparks; paragraph 39) and said steps (a) and (c) are performed via a secure link through said network (Sparks; paragraph 71).

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 23, 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sparks (U.S. Patent Publication No. 2001/0037215) in view of Snell (U.S. Patent No. 5,722,999).

A. As per claim 23, Sparks discloses the method of claim 20 wherein said step (a) includes the sub-step of: providing an id number for the medical test device; and recording the id number prior to transmitting the test device to the end user.

Sparks fails to expressly teach to provide and record an id number for the medical test device, per se, since it appears that Sparks is more directed to provide information and medical device to the patient. However, this feature is well known in the art, as evidenced by Snell.

In particular, Snell discloses a system and method for storing and displaying historical medical data measured by an implantable medical device, wherein unique identifier code is stored in the program memory area (Snell; col. 4, lines 21-23 and 27-29 and col.7, lines 38-41).

It would have been obvious to one having ordinary skill in the art at the time of the invention to have combined distribution system disclosed by Sparks within the stored unique identifier number taught by Snell with the

motivation of the identifier code identifies the implanted or distributed medical device as a device implanted in or distributed to a particular patient (Snell; col. 7, lines 41-42).

B. As per claim 24, Sparks discloses the method of claim 20 wherein said step (a) comprises:

(a1) authorizing a requestor to make a request to transmit the test device to the patient (Sparks; paragraph 42);

(a2) accepting a request from the requestor to transmit the test device to the patient (Sparks; paragraph 42);

(a3) recording a unique identification number for the test device;
and

(a4) communicating with a logistics system or a carrier to transport the device to the patient (Sparks; paragraph 62).

Sparks fails to expressly teach recording an id number for the medical test device, per se, since it appears that Sparks is more directed to provide information and medical device to the patient. However, this feature is well known in the art, as evidenced by Snell.

In particular, Snell discloses a system and method for storing and displaying historical medical data measured by an implantable medical device, wherein unique identifier code is stored in the program memory area (Snell; col.7, lines 38-41).

It would have been obvious to one having ordinary skill in the art at the time of the invention to have combined distribution system disclosed by Sparks within the stored unique identifier number taught by Snell with the motivation of the identifier code identifies the implanted or distributed medical device as a device implanted in or distributed to a particular patient (Snell; col. 7, lines 41-42).

11. Claim 25, 36 and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sparks (U.S. Patent Publication No. 2001/0037215) in view of applicant's admitted prior art.

A. As per claim 25, sparks discloses the method of claim 20 further including the step of: (d) tracking the time following completion of said step (a) and initiating step (b) within a fixed time period.

Sparks fails to expressly teach to track the time between providing and collecting the medical device, per se, since it appears that Sparks is more directed to provide information and medical device to the patient.

However, this feature is well known in the prior art admitted by the applicant.

In particular, applicant's prior arts U.S. Patent No's 5,797,852 and 5,844,996 disclose devices to provide feedback to physicians following a period of in-home testing by a patient, wherein the patient carries the device home for a one-night test.

It would have been obvious to one having ordinary skill in the art at the time of the invention to have combined distribution system disclosed by Sparks within the tracking the time between providing and collecting the test with the motivation of the providing feedback to physicians following a period of in-home testing by a patient. (Applicant's specifications; page 3, lines 7-9).

B. As per claim 36, Sparks discloses a method for conducting a medical test for an authorized physician (Sparks; paragraph 3), comprising:

- (a) collecting an order for a device (Sparks; paragraph 16);
- (b) transmitting a medical test device to a user (Sparks; paragraph 3);
- (c) extracting test results from the test device;
- (d) retrieving the test device from the user subsequent to the user inputting test results into the device; and
- (e) distributing test results to authorized recipients (Sparks; paragraph 38).

Sparks fails to expressly teach to extract the test results from the medical device and also retrieving the test device from the user, per se, since it appears that Sparks is more directed to obtain the results from the patient. However, this feature is well known in the prior art admitted by the applicant.

In particular, applicant's prior arts U.S. Patent No's 5,797,852 and 5,844,996 disclose devices to provide feedback to physicians following a period of in-home testing by a patient, wherein the patient carries the device to the physician, who extracts data from the device.

It would have been obvious to one having ordinary skill in the art at the time of the invention to have combined distribution system disclosed by Sparks within the extracting the results from the device with the motivation of the providing feedback to physicians following a period of in-home testing by a patient. (Applicant's specifications; page 3, lines 7-9).

C. As per claim 51, Sparks discloses a method for conducting a medical test for an authorized physician (Sparks; paragraph 3), comprising:

- (a) collecting an order for a device input via a computer and received via a communications network (Sparks; paragraph 18);
- (b) transmitting a medical test device to a patient at a patient defined location (Sparks; abstract and paragraph 3);
- (c) extracting test results from the test device;
- (d) retrieving the test device from the patient subsequent to the user inputting test results into the device (Sparks; paragraph 37); and
- (e) distributing test results to authorized recipients via a secure connection to said communications network (Sparks; paragraph 38).

The obviousness of modifying the teaching of Sparks to include the extracting test results from the test device (as taught by applicant's

admitted prior art) is as addressed above in the rejection of claim 36, part (c) and incorporated herein.

12. Claim 41 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sparks (U.S. Patent Publication No. 2001/0037215) in view of Kulkarni (U.S. Patent Publication No. 2001/0032098).

A. As per claim 41, Sparks discloses a system for providing a test system to a patient, comprising:

- i. an interface server including an ordering interface coupled to a communications network accessible by a plurality of computers (Sparks; paragraph 18);
 - ii. a database server coupled to the interface server (Sparks; paragraph 65);
 - iii. a logistics system transmitting a medical test to a patient at the direction of a physician accessing the ordering system via the interface server and retrieving the test from the patient upon completion of the test (Sparks; paragraph 37); and
 - iv. a data transfer system, collecting test results from the medical test and distributing results via a secure mechanism to an authorized recipient.
- Sparks fails to expressly teach a data transfer system, collecting test results from the medical test and distributing results via a secure mechanism to an authorized recipient, per se, since it appears that Sparks

is more directed to obtain the results from the patient. However, this feature is well known in the art, as evidenced by Kulkarni.

In particular, Kulkarni discloses an internet ready medical device, wherein a control box can be modified to send the readings over the internet (Kulkarni; paragraph 36).

It would have been obvious to one having ordinary skill in the art at the time of the invention to have combined distribution system disclosed by Sparks within sending the readings over the internet taught by Kulkarni with the motivation of to determine the appropriate action to be taken depend on the reading (Kulkarni; paragraph 36).


Conclusion

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The cited but not disclosed arts teach "Electronic system for tracking and monitoring articles to be sterilized and associated method" 2003/0170901, "Personalized health care provider directory" 6,014,629, "Method and apparatus for electronically accessing and distributing personal health care information and services in hospitals and homes" 5,867,821, "Automated system for identifying authorized system users" 5,689,247, "Delivery of medical services using electronic data communications" 5,619,991, "Portable non-invasive testing apparatus" 5,257,627, "Device for obtaining, transporting and using a liquid specimen" 4,596,157.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dilek B. Cobanoglu whose telephone number is 571-272-8295. The examiner can normally be reached on 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on 571-272-6776. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Dilek B. Cobanoglu
Art Unit 3626


JOSEPH THOMAS
SUPERVISORY PATENT EXAMINER